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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

NAFF, DAVID M

ART UNIT PAPER NUMBER

1651

DATE MAILED: 05/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/843,295

Applicant(s)

CAPLICE ET AL.

Examiner

David M. Naff

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

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DETAILED ACTION

In view of new references applied, the final rejection of 2/17/04 of withdrawn and prosecution on the merits is reopened.

The amendment of 4/19/04 amended claim 1.

5 Claims examined on the merits are 1-37, which are all claims in the application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

0 The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5 Claims 10, 11 and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

0 Dependent claim 10 requires the non-woven framework of claim 1 to be attached to at least a portion of the exterior surface of a stent that is the medical device of claim 1. However, the specification does not appear to describe attaching the non-woven framework to an exterior surface of a stent. It is uncertain how this is performed and the kind of structure obtained after such attachment.

5 Dependent claim 11 is unclear how it further limits the stent of dependent claim 9 by requiring the stent to be fabricated from the

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non-woven framework of the medical device which is required in claim 1 on which claim 9 is dependent. Due to claim 9 requiring the medical device of claim 1 to be a stent, it appears the stent of claim 9 will inherently be fabricated from the non-woven framework, and there is seen no other way it can be fabricated. A dependent claim does not further limit a previous claim when the dependent claim requires only what is inherent in the previous claim.

Dependent claim 31 is unclear by requiring the non-woven framework to be fused to at least a portion of at least one of the plurality of surfaces of the medical device of claim 12. The specification does not appear to describe fusing the framework to a surface, and it is uncertain how this occurs and the kind of structure obtained after fusing the framework to the surface.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 12, 14, 16-20, 26 and 28 are rejected under 35 U.S.C. 102(e) as being anticipated by Vacanti et al (6,348,069 B1) (newly applied).

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The claims are drawn to an implantable medical device comprising cells and a plurality of surfaces, wherein at least one of the surfaces comprises a non-woven framework of fibers having an average size of at least 40 μm , and the device is implantable within the vascular system of a mammal.

Vacanti et al disclose forming an implantable matrix structure that can be tubular in the form of a blood vessel (col 7, lines 42-43) and be formed of a fibrous polymeric matrix (col 3, lines 42-43) that can be non-woven (col 3, line 51), have pores of 100-300 microns (col 3, line 57), and be seeded with cells including smooth muscle cells or fibroblasts (col 6, lines 26-31). The polymer can be polyglycolic acid (col 4, line 9) and be coated with a polymer that enhances cell attachment such as fibronectin (col 5, line 25). The matrix structure may also contain growth factors (col 5, lines 59-65).

When the matrix structure of Vacanti et al is tubular in the form of a blood vessel, it inherently has a plurality of sides and is implantable in the vascular system of an animal. The structure can be non-woven and have a pore size as claimed. When in the form of a blood vessel, it is inherently a vascular graft as in claim 28.

Claim Rejections - 35 USC § 103

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Vacanti et al ('069).

The claim requires the polymer to be polyethylene terephthalate or polytetrafluoroethylene.

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Vacanti et al disclose that it known to make vascular grafts from polytetrafluoroethylene (col 2, line 33).

It would have been obvious to use polytetrafluoroethylene as the polymer of Vacanti et al when the characteristics of this polymer is
5 desired since it is a known polymer for producing vascular grafts.

Claim Rejections - 35 USC § 103

Claims 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vacanti et al ('069) in view of Ferrara et al (6,455,283 B1).

10 The claims require cells that express a polypeptide such as vascular endothelial growth factor.

Ferrara et al disclose transforming cells to produce vascular endothelial cell growth factor with a nucleic acid encoding the factor.

15 It would have been obvious to use as the cells of Vacanti et al cells that are encoded to produce a growth factor as taught by Ferrara et al since Vacanti et al disclose providing growth factors in the matrix (col 5, lines 59-62).

Claim Rejections - 35 USC § 103

20 Claims 12, 14-20 and 26-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vacanti et al in view of Healy et al (5,670,161) (newly applied).

Claims 27 and 29 require the device to be in the form of stent.

Vacanti et al is described above.

Healy et al disclose an expandable stent (col 12, line 46) that is non-woven (col 12, line 63) and is formed from fibers (paragraph bridging cols 9 and 10).

It would have been obvious to form the structure containing cells of Vacanti et al as a stent from un-woven fibers as disclosed by Healy et al since a stent is tubular and Vacanti et al suggest forming tubular structures containing cells from un-woven fibers.

Claim Rejections - 35 USC § 103

Claims 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 12, 14-20 and 26-29 above, and further in view of Ferrara et al.

The invention and Ferrara et al are described above.

When producing the structure containing cells of Vacanti et al as a stent from un-woven fibers as set forth above, it would have been obvious to use cells that are encoded to produce a growth factor as taught by Ferrara et al since Vacanti et al disclose providing growth factors in the matrix of the structure (col 5, lines 59-62).

Claim Rejections - 35 USC § 103

Claims 1-7, 9-13, 18-20 and 24-34 rejected under 35 U.S.C. 103(a) as being unpatentable over Vacanti et al ('069) in view of Healy et al ('161) and Ducheyne (5,670,1612) and Cottone Jr (5,824,043) (newly applied).

Claims 1 and 32 require the device to be contain a non-woven framework make of metal fibers, and claim 12 encompasses a device containing a non-woven framework of metal fibers.

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Vacanti et al and Healy et al are described above.

Ducheyne disclose a porous metal material for surgical implantation made of metal fibers such as stainless steel or titanium (col 12, lines 45-46), and having a pore size of at least 150 micrometers (col 12, lines 49-50). The material is made by sintering fibers together (col 7, lines 25-45). As shown by Figure 1, the material is non-woven.

Cottone Jr discloses an expandable stent (col 3, lines 35 -40) made of metal strands (col 4, lines 1-5 and col 6, lines 12-18) or polymers (col 6, lines 18-21).

It would have been obvious to form the structure containing cells of Vacanti et al as a stent from un-woven fibers as disclosed by Healy et al since a stent is tubular and Vacanti et al suggest forming tubular structures containing cells from un-woven fibers. It would have been additionally obvious to use metal fibers as the fibers as suggested by Ducheyne using metal fibers to form an implant and Cottone Jr using metal stands or polymers to form a stent. Using metal fibers would have been obvious when the properties of metal fibers are desired as compared to properties of fibers made from a polymer.

Claim Rejections - 35 USC § 103

Claims 8, 21-23 and 35-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 1-7, 9-13, 18-20 and 24-34 above, and further in view of Ferrara et al ('283).

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The claims require cells that express a polypeptide such as vascular endothelial growth factor.

Ferrara et al disclose transforming cells to produce vascular endothelial cell growth factor with a nucleic acid encoding the
5 factor.

When forming the structure containing cells of Vacanti et al as a stent and using metal fibers as set forth above, it would have been obvious to use cells encoded to produce vascular endothelial growth factor as taught by Ferrara et al since Vacanti et al can have growth
10 factors present in the matrix of the structure (col 5, lines 59-62).

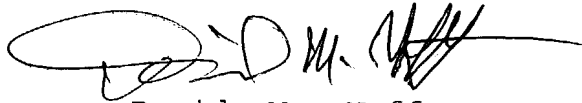
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be
15 reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



David M. Naff
Primary Examiner
Art Unit 1651

DMN
5/5/04